REMARKS

This Reply is timely filed and responsive to the Office Action mailed September 7, 2005. Claims 1-16 were pending at the time of the Office Action. In this Reply, claims 1, 4, 7, and 11 have been amended, and claims 5 and 15 have been cancelled. No new matter has been added.

Claims 1, 3 and 7 were rejected under 35 U.S.C. 112, paragraph 2. The amendments to claims 1 and 7 overcome the 112 paragraph 2 rejections to claims 1, 3 and 7.

Turning now to claim rejections based on cited art, claims 1, 2 and 11-13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Sepponen, U.S. Patent No. 4,641,659. Claims 1-3, 5, 11 and 15 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/778,973 (U.S. Patent Application Publication No. 2004/0067399). Claims 1-5, 8, 11, and 14-16 were rejected under 35 U.S.C. § 102(e) as being anticipated by Wang (US 6,567,688). Claims 6, 7, 9 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wang in view of Bolstad et al., U.S. Patent No. 5,630,154.

Before reviewing the claim rejections based on cited art, Applicants will review the claimed invention as now recited in amended claim 1. Amended claim 1 recites a method of examining biological tissue, and includes the steps of radiating a tissue region with a plurality of microwave radiation pulses which span a range of microwave frequencies of at least 600 MHz, wherein the tissue region emits a plurality of thermoacoustic signals in response. At least one image of the tissue region is then formed from the plurality of thermoacoustic signals. Support for the 600 MHz limitation can be found in the third sentence of paragraph 36.

The plurality of radiation pulses used thus span a range of microwave (carrier) frequencies of at least 600 MHz, thus providing at least two (2) frequencies having ultrawideband spacing, wherein the tissue region emits a plurality of thermoacoustic signals

responsive to the ultrawideband stimulation. At least one image of the tissue region is formed from the plurality of thermoacoustic signals received which span the range of carrier frequencies. In the embodiment now claimed in claim 4, the plurality of radiation pulses span a frequency range of at least 1 GHz. (Support in paragraph 23; copied below)

[0023] A microwave is generally defined as an electromagnetic wave having a wavelength from 300 mm to 10 mm, corresponding to a frequency of 1 GHz to 30 GHz. The microwave frequency generally regarded as a carrier frequency, and the beam is generally defined by the radiation pattern. The microwave pulses are generally in a frequency range from about 1 GHz to 10 GHz to provide sufficient penetration depth into normally lossy biological tissue. The range of microwave frequencies preferably spans a frequency range of at least 1 GHz. For systems according to the invention, the microwave pulse width will generally be on the μs order.

Applicants note that the inventive method claimed herein relates to *thermoacoustic imaging* which is based on analysis of induced *acoustic (sound)* waves, which is highly distinct in both physics, methodology as well as required instrumentation as compared to conventional microwave imaging. In conventional microwave imaging, microwave irradiation induces reflected microwave signals from the irradiated tissue (e.g. breast tissue) which is received by an antenna which converts the emanated electromagnetic (microwave) signal to an electrical signal. In contrast, in the claimed thermoacoustic imaging, microwave irradiation is used which induces the irradiated tissue to emanate thermoacoustic signals which are collected by an acoustic transducer, such as a piezoelectric based transducer array 125 which converts the sound waves to an electrical signal. Paragraph 12 copied below describes details regarding thermoacoustic imaging:

[0012] In operation, microwave-induced thermoacoustic imaging involves the use of a short-pulsed microwave beam for irradiating the biological tissue of the breast. The breast tissue can absorb the microwave energy and, responsive to the absorption of the microwave energy, the breast tissue can emanate thermoacoustic waves through thermoelastic expansion. The thermoacoustic waves can carry the information regarding the microwave energy absorption properties of the breast tissue under irradiation. The different energy absorption properties among the different types of breast tissue permit the construction of a distribution of microwave energy absorption pattern in a homogeneous acoustic medium.

The data set provided by stimulating radiation over the claimed ultrawideband range of frequencies according to the invention is quite large as compared to the data provided by conventional single frequency stimulation. For processing such data, the application describes methods for the highly complex task of forming images from such a large amount of data, such as using a *significant and non-obvious modification* of a preferred adaptive beamformer, the Robust Capon Beamformer (RCB). The original RCB is disclosed in an article by inventor Jian Li and Z. Wang entitled "On robust Capon beamforming and diagonal loading. Specifically, the inventors discovered how to utilize the large data set collected from a plurality of different stimulating frequencies, such as to form a single image, using a modified RCB, as described in paragraph 62 (copied below).

> [00062] Application specific factors for thermoacoustic imaging according to the invention require extending the RCB algorithm to wideband signals. As disclosed in U.S. Application No. 10/358,597, the RCB algorithm is generally described for narrowband signal. To extend the RCB for application to wideband signals, a wideband signal can be divided into several narrowband frequency bins, and the RCB applied to each bin. Thus, the relatively wideband thermoacoustic signal can be treated as comprising a plurality of narrow pulses with the arrival time and pulse duration approximately known. Through time gating, a large portion of signal interferences can be removed before applying the RCB.

Turning now to the cited art, according to the Examiner regarding Sepponen:

> Sepponen teaches a method of and apparatus for examining biological tissue including radiating a region of tissue with microwave radiation pulses from a horn antenna that are swept across a range of microwave frequencies, where the tissue region may be breast tissue and emand emits thermoacoustic signals responsive to the microwave pulses that are received by an acoustic ustic transducer array, which then provides electrical signals in response, and forming at least one ıst one image of the tissue region from the thermoacoustic signals, where structure is provided to 1 to translate the transducer array and/or the antenna (col. 2, lines 32-56 and col. 3, lines 6-26).

translate the transducer array and/or the antenna (col. 2, lines 32-56 and col. 3, lines 6-26).

Applicants respectfully disagree with the characterization of Sepponen above. Sepponen discloses a microwave apparatus for diagnosis of cancer of the breast including a microwave transmitter and a microwave antenna for directing a microwave signal to the breast under examination, and a microwave receiver having amplitude and phase shift detectors for receiving of reflected microwave signals. A processor is connected to the receiver for processing the amplitude and phase information to detect and locate cancer in the breast. A matching plate having a dielectric constant substantially the same as normal breast tissue is located between and in engagement with the breast and antenna. The antenna engages and sweeps over the plane surface of the matching plate to eliminate any air gap in the transmission path. A display unit is connected to the processor to create a microwave image of cancer growth, if any.

Sepponen thus clearly relates to conventional microwave imaging where microwaves are both transmitted and received. Although in one embodiment Sepponen discloses pulsed operation, Sepponen does not disclose or suggest using a plurality of radiation pulses which span a range of frequencies. Moreover, Applicants have copied col. 2, lines 32-36 and col. 3 lines 6-26 of Sepponen cited by the Examiner to demonstrate that thermal acoustics are not disclosed or suggested.

col. 2, lines 32-39:
The apparatus of the invention for diagnosing cancer of the breast comprises, as components previously known in themselves, a microwave transmitter, a microwave wave antenna for the purpose of directing a microwave signal to the object under examination, a microwave receiver with amplitude and phase shift detectors, and a processor for processing the amplitude and phase information.

col. 3 lines 6-26:
As is well known, the shape, size and other characteristics of breast vary extensively. Since in microwave image forming it must be possible to match the transmitter and receiver with the skin and the subcutaneous fat with a view to avoiding unnecessary reflections, there has been provided, in the apparatus, a matching plate 3, which has been made of a material having a

dielectric constant Er equal to the average dielectric constant of breast tissue (about 5). The breast to be examined, 1, is pressed against this matching plate 3. On the underside of the plate 3, the area to be examined is scanned with the microwave antenna system 4, governed by the scanning mechanism 6. The apparatus comprises, furthermore, a microwave transmitter 7 and a microwave receiver, with amplitude detector 8 and phase difference detector 9. The amplitude and phase information obtained from these is conveyed to the processor 10, which forms of the object under examination a microwave image, which is displayed with the display unit 11. In the case that there is a neoplasm 2, a conforming shadow 2' will be seen in the image in the display unit.

Accordingly, amended claims 1 and 10 and their respective dependent claims which recite thermoacoustic imaging using a plurality of radiation pulses spanning a range of microwave frequencies of at least 600 MHz, and forming at least one image of the tissue region from the plurality of thermoacoustic signals are patentable over Sepponen.

Claims 1-5, 8, 11, and 14-16 are rejected under 35 U.S.C. § 102(e) as being anticipated by Wang (US 6,567,688). Regarding Wang, the Examiner asserts that:

Wang teaches a method of and apparatus for examining biological tissue including radiating a region of tissue with microwave radiation pulses that are swept across a range of microwave frequencies, where the tissue region may be breast tissue and emits thermoacoustic signals responsive to the microwave pulses that are received by an acoustic transducer array, which then provides electrical signals in response, and where the radiation pulses span a frequency range of at least 1 GHz, are ultrawideband signals and include a plurality of polarizations, and forming at least one image of the tissue region from the thermoacoustic signals, where the at least one image comprises a plurality of images from fractional portions of the tissue that are combined to form an overall image (col. 1, lines 19-32, col. 2, lines 8-27 and 41-45, col. 4, lines 20-26, col. 5, lines 31-43, col. 8, lines 24-52, col. 9, lines 62-67, col. 10, lines 1-3, col. 12, lines 50-67 and col. 13, lines 1-36).

Applicants respectfully disagree with many of the assertions above regarding Wang. Wang discloses a microwave-induced thermoacoustic tomography system and method to image biological tissue. Microwave pulses are used to irradiate tissue to generate acoustic waves by thermoelastic expansion. The microwave-induced thermoacoustic waves are detected with an ultrasonic transducer or transducer array. Each time-domain signal from the ultrasonic transducer is converted to a one-dimensional image along the acoustic axis of the ultrasonic transducer. Scanning the system perpendicularly to the acoustic axis of the ultrasonic transducer generates multi-dimensional images in real time without computational image reconstruction.

Contrary to the Examiner's assertions, Wang does not disclose or suggest "radiation pulses span a range of at least 1 GHz", or ultrawideband stimulating signals. First, ultrawideband is not mentioned once in Wang. Second, the pulse widths disclosed in Wang as noted below of 0.1 μs to 0.5 μs is way too long to be considered to be ultrawideband signals. Moreover, Wang exclusively teaches use of a single microwave pulse frequency generally in the range from 300 MHz to 3 GHz not "radiation pulses span a range of at least 1 GHz" as asserted by the Examiner as clearly taught in col. 5 lines 22-30 (copied below).

> The frequency of the microwave energy should be selected based upon the required imaging depth for a specific problem. See FIG. 1. A higher frequency may be selected for imaging thin tissues, and vice versa. In the embodiment of FIG. 1, the microwave frequency is preferably within the range of 300 MHz to 3 GHz, and the pulse width is preferably within the range of 0.1 μs to 0.5 μs. Unless otherwise stated, the exemplary embodiment described below has a frequency of 3 GHz and a pulse width of 0.5 μs.

Wang also teaches away from the use of two or more pulse frequencies. First, Wang's use of a waveguide (e.g. waveguide 14 in Fig. 2; waveguides 14a and 14b in Fig. 9) clearly evidences use of a single pulse frequency as well. As known in the art, waveguides can transmit only one modulation frequency at a time. Second, use of two or more microwave pulse frequencies leads to significant computational complexity. The single pulse frequency

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determines the nominal imaging depth. To cover several penetration depths and to generate 1D, 2D and 3D images, Wang explicitly discloses mechanical movement to provide scanning about the nominal imaging location, rather than use of multiple microwave frequencies according to the present invention. Col. 6, lines 8-23 of Wang regarding scanning is copied below:

Although scanning is accomplished in the embodiment of FIG. 2 by translating the sample relative to the transducer, it will be understood that the same effect can be achieved by translating the ultrasonic transducer relative to the sample. Indeed, in the case of breast cancer screening or other in vivo human or animal imaging, it would normally be preferable to translate the transducer relative to the tissue region being imaged. As used herein, therefore, the term "scanning" is intended to encompass both translation of the sample tissue and translation of the transducer.

Accordingly, Wang teaches use of a single pulse frequency selected to provide a desired imaging depth. Neighboring tissue in the z (depth) direction is then imaged using mechanical motion of the tissue sample or transducer.

Accordingly, although unlike Sepponen Wang has some relation to the claimed invention as it relates to thermoacoustic imaging, Wang teaches a method of examining biological tissue using a plurality of pulses all at a single pulse frequency and as demonstrated above clearly teaches away from the claimed method of examining biological tissue comprising radiating a tissue region with a plurality of microwave radiation pulses which span a range of microwave frequencies, such as the claimed at least 600 MHz. Therefore, Applicants submit that amended claims 1 and 10 and their respective dependent claims are patentable over Wang.

Turning now to the issue of double patenting, as noted above, Claims 1-3, 5, 11 and 15 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/778,973 (U.S. Patent Application Publication No. 2004/067399). According to the Examiner:

3. Claims 1-3, 5, 11 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-4 of copending Application No. 10/778,973 (U.S. Patent Application Publication No. 2004/0167399). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method as disclosed in the '973 application teaches all of the steps claimed in Claims 1 and 11 of the present application, thus the broader language of Claims 1 and 11 of the present application is anticipated by the more specific language of the '973 application. Similarly, the '973 application teaches the features of each of the dependent Claims 2, 3, 5 and 15 of the present application.

Applicants respectfully traverse the asserted provisional double patenting rejection. Claims 1-4 of copending Patent Application Publication No. 20040167399 is copied below:

1. A method for detecting breast cancer comprising the steps of: positioning a transmitting antenna and a receiving antenna about a breast so that said transmitting antenna is positioned to transmit microwave energy into said breast and said receiving antenna is positioned to receive said transmitted energy after said energy has passed into said breast; transmitting microwave energy from said transmitting antenna; receiving microwave energy via said receiving antenna; adjusting a relative position of said transmitting antenna and said receiving antenna about said breast; and repeating said transmitting and said receiving steps after adjusting said relative position, wherein the received microwave energy is used to determine a presence of tumors within said breast.

2. The method of claim 1, wherein said transmitted step transmits ultrawideband microwave energy using a stepped frequency transmission technique.

3. The method of claim 1, performing said adjusting and said repeating steps a plurality of times to generate a composite scan of said breast.

4. The method of claim 3, further comprising the step of: displaying an image of said breast using microwave imaging based upon said received microwave energy.

Like Sepponen, copending Published Patent Application Publication No. 20040167399 clearly relates entirely to conventional microwave imaging, where microwave irradiation induces reflected microwave signals from the irradiated tissue (e.g. breast tissue) and is received by an antenna which converts the electromagnetic (microwave) signal to an electrical signal. The claimed thermoacoutic imaging method and system are thus not derivable from Published Patent Application Publication No. 20040167399 and as a result cannot reasonably be considered to be

obvious based on 20040167399. Accordingly, Applicants submit that the asserted double patenting rejections are improperly based and therefore should be removed.

Applicants have made every effort to present claims which distinguish over the cited art, and it is believed that all claims are clearly in condition for allowance. However, Applicants invite the Examiner to call the undersigned if it is believed that a telephonic interview (direct line (561) 671-3662) would expedite the prosecution of the application to an allowance. Although no fee is believed to be due, the Commissioner for Patents is hereby authorized to charge any deficiency in fees due or credit an excess in fees with the filing of the papers submitted herein during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,

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